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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/593,591

06/13/2000

Gary K. Michelson

101.0078-00000

5619

22882 7590 02/12/2007
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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/593,591

Applicant(s)

MICHELSON, GARY K.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7-20,22-30,32-44,46,47,49-86,88,89,91-129,148-164,166,168-184,186,188-204,206,208-224,226,228-264,266 and 268-282.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 43,44,46,47,49-84,153,154-157,183,184,186,188-202 and 243-262.

Continuation of Disposition of Claims: Claims rejected are 1,2,4,5,7-20,22-30,32-42,85,86,88,89,91-129,148-152,155-164,166,168-182,203,204,206,208-224,226,228-242,263,264,266 and 268-282.

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Election/Restrictions

Claims 43, 44, 46, 47, 49-84, 153, 154-157, 183, 184, 186, 188-202, and 243-262 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on January 26, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 7-20, 22-30, 32-42, 85-86, 88, 89, 91-129, 148-152, 158-164, 166, 168-182, 203, 204, 206, 208-224, 226, 228-242, 263, 264, 266, and 268-282 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The language added to the independent claims (i.e. "said opening having a perimeter located closer to said leading end than said trailing end") by the November 10, 2006 amendment does not have clear original support or antecedent basis from the specification. The Examiner agrees that such language has a species that has inherent support in that "a point of the perimeter closest to the leading end is also farther away

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from the trailing end.” Only this language has clear original support since the drawings were not drawn to scale. The new language of the claim, however, does not have original support because it encompasses structures not clearly before contemplated. In particular, it encompasses and leads one to believe that the distance of the closest point of the perimeter to the leading edge is actually a smaller distance than the corresponding point on the trailing edge.

It is noted that the drawings are not drawn to scale so the Applicant cannot rely on the dimensions thereof to show actual distances or distance ratios. For example, the Applicant cannot claim that the perimeter point closest to the leading end is a smaller distance therefrom than the respective perimeter point closest to the trailing end is from the trailing end; see MPEP 2125 that is incorporated herein by reference.

Upon review of the portions of the original specification that Applicant relies on for support of the language (i.e. Figures 1, 8, and 10 as well as page 8, lines 5-17 and page 9, line 17 to page 10, line 4), it is noted that the drawings do not clearly show the closest corresponding points as being different. Moreover, the specification citations deal with the outer perimeter and not the perimeter of the opening as claimed so they are irrelevant thereto.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4, 5, 7-20, 22, 25, 30, 32-35, 85, 86, 88, 89, 91-106, 109, 114-119, 127-129, 148, 158, 163, 164, 171, 174, 175, 179, 180, 203, 204, 206, 208-211, 213-215, 219, 220, 223, 224, 226, 228-231, 233-235, 239, 240, 263, 264, 266, 268-271, 273-275, 279, and 280 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Thalgott (US 5,865,845). Boyle discloses a bone ring obtained from a long bone (Figures 5, 10, 12, and column 2, lines 28-55). It can be taken from the long bone by parallel cuts and formed into any shape; see column 4, lines 29-57, particularly lines 54-57. Upon review of the drawings of Boyle, it is clear that the distance between the point of the perimeter closest to the leading end is smaller than the distance between the that same point is to the trailing end; the feature is pronounced enough that one can say that such a relationship exists even though the drawings are not drawn to scale. However, Boyle does not disclose the particular structure of parallel sides and non-linear trailing end between parallel lines as claimed.

However, Thalgott teaches that such a prosthetic intervertebral disc shape was known to the same art; see Figures 2, 4, 6, and 8. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to form the Boyle device into the shape disclosed by Thalgott so that advantages taught by Thalgott (see column 1, line 11 to column 2, line 20) can be incorporated into Boyle's invention. The modifier "generally" for straight is considered a broad term that is reads on the disclosure of Figures 10 and 12 of Boyle, which is slightly curved. Alternatively, the new

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"generally straight" limitation reads on the ridges (24) and grooves (28) or equivalent of Boyle, which elements run alongside the perimeter of the trailing edge.

Regarding claims 25 and 109, the plural openings are the pores in the bone that are naturally present in such material.

Claims 26-29, 110-113, 149-152, 155-157, 159-162, 172, 177, 178, 182, 212, 217, 218, 222, 232, 237, 238, 242, 272, 277, 278, and 282 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) and Thalgott as applied in the previous rejection, further in view of Kozak et al (US 5,397,364). Boyle fails to disclose the screw holes and screws as claimed. However, Kozak teaches that it was known to put multiple bone screws in similar implants as a means to secure them; see Figures 24 and 25 and the textual description of these figures. Therefore, it is the Examiner's position that it would have been obvious to use bone screws and have holes for them in the Boyle implant for the same reasons that Kozak uses the same: to secure the implant to the adjacent bone.

With regard to claims 28 and 29, it is the Examiner's position that it would have been prima facie obvious to make the bone screws and other bone implant components out of bone because the ring itself is made of that material. Since the ring itself is made of bone material, it would have been obvious to make the other parts of the implant out the same material because it would have all the advantages and purposes that led Boyle to make the bone ring out of bone or composites of bone.

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With regard to claim 155, it is the Examiner's position that it would have been prima facie obvious to have more than two bone screw openings since both one and two bone screws and their openings are taught by Boyle.

Claims 36-42, 120-126, 166, 168-170, 173, 181, 206, 221, 241, and 281 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al in view of Thalgot as applied in the rejection of claim 1 above in further view of the suggestions of Boyle (US 6,277,149). Boyle et al fails to disclose the types of growth promoting substances claimed. However, the Examiner posits that the type of growth promoting substance would have been prima facie obvious over Boyle et al because there is no criticality for such types shown or demonstrated. For example, in column 4, lines 10-13, Boyle discloses putting bone growth material into the opening (26). The specific type of bone implant material claimed would amount to a substitution of a functionally equivalent bone growth material for another one as disclosed by Boyle. For this reason, it would have been prima facie obvious to an ordinary artisan to substitute one bone growth material for another since the other one would function equally well.

Claims 23, 24, 107, 108, 176, 196, 216, 236, 256, and 276 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Zdeblick et al (US 5,669,909)*. Boyle et al meets or renders obvious the claim language but fails to disclose more than one bore through the upper and lower surfaces as claimed. Zdeblick et al, however, teaches that it was known to have more than one hole in similar implants; see the figures. Hence, it is the Examiner's position that it would have been

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obvious to have two or more holes in the Boyle et al implant for the same reasons that Zdeblick et al has the same and in order to promote greater ingrowth.

*It is noted that the Examiner inadvertently left out the Thalgott teaching as used in the previous three rejections. However, it should have been clear to one reviewing the action that this oversight was inadvertent. In order to advance prosecution, the Examiner will not change the literal ground of rejection herein. Nonetheless, the claims are considered unpatentable for the reason that the first prior art rejection above is obvious in view of Zdeblick et al.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are unpersuasive. The rejection has been further explained to point out how the newly claimed feature is inherently disclosed by Boyle; see the underlined portion thereof.

Particularly, the language added to the independent claims (i.e. "said opening having a perimeter located closer to said leading end than said trailing end") by the November 10, 2006 amendment does not have clear original support or antecedent basis from the specification. The Examiner agrees that such language has species that has inherent support in that "a point of the perimeter closest to the leading end is also farther away from the trailing end." Only this language has clear original support since the drawings were not drawn to scale. The new language of the claim, however, does not have original support because it encompasses structures not clearly before contemplated. In particular, it encompasses and leads one to believe that the distance

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of the closest point of the perimeter to the leading edge is actually a smaller distance than the corresponding point on the trailing edge.

It is noted that the drawings are not drawn to scale so the Applicant cannot rely on the dimensions thereof to show actual distances or distance ratios. For example, the Applicant cannot claim that the perimeter point closest to the leading end is a smaller distance therefrom than the respective perimeter point closest to the trailing end is from the trailing end; see MPEP 2125 that is incorporated herein by reference.

Upon review of the portions of the original specification that Applicant relies on for support of the language (i.e. Figures 1, 8, and 10 as well as page 8, lines 5-17 and page 9, line 17 to page 10, line 4), it is noted that the drawings do not clearly show the closest corresponding points as being different. Moreover, the specification citations deal with the outer perimeter and not the perimeter of the opening as claimed so they are irrelevant thereto.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738